

PCT

PTO/SB/21 (09-04)

Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

**TRANSMITTAL
FORM**

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	10/534,791
Filing Date	12 May 2005
First Named Inventor	Peter G. KLIMKO et al.
Art Unit	
Examiner Name	
Attorney Docket Number	2444 US F

ENCLOSURES (Check all that apply)

- ☐ Fee Transmittal Form
- ☐ Fee Attached
- ☐ Amendment/Reply
- ☐ After Final
- ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☒ Information Disclosure Statement

- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation
- ☐ Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
- ☐ Landscape Table on CD

- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
- ☐ Proprietary Information
- ☐ Status Letter
- ☒ Other Enclosure(s) (please identify below):

corresponding PCT/US03/38678
Search Report [3 pp]; 24
References and Return Card.

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Alcon Research, Ltd.		
Signature	<i>Teresa J. Schultz</i>		
Printed name	Teresa J. Schultz		
Date	8 Nov. 2005	Reg. No.	40,526

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature	<i>Barbara McKenzie</i>		
Typed or printed name	Barbara McKenzie	Date	8 November 2005

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Peter G. KLIMKO et al.

Serial No: 10/534,791

Filed: 12 May 2005

Examiner:

Group Art Unit:

FOR: SUPEROXIDE DISMUTASE MIMICS FOR THE TREATMENT OF OCULAR
DISORDERS AND DISEASES

**INFORMATION DISCLOSURE STATEMENT
PURSUANT TO 37 C.F.R. 1.56, 1.97, AND 1.98**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. 1.56, 1.97, and 1.98, Applicants submit the patents, articles, and other information referenced in the specification as filed. The references are listed on the attached PTO Form 1449. Copies of the U.S. patents are not enclosed in accordance with 37 CFR 1.98(a)(2).

A copy of the International Search Report issued in the PCT application, of which the present application is a corresponding application, is also included for the Examiner's convenience.

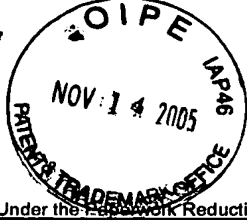
Applicants request that the listed patents, articles, and other information be considered during prosecution of this application and that they appear among the "References Cited" on any patent issuing herefrom.

Respectfully submitted,

8 NOV. 2005
Date

By: Teresa J. Schultz
Teresa J. Schultz
Registration No. 40,256
817-551-4231

Address for Correspondence:
Alcon Research, Ltd.
Attn: Teresa J. Schultz
6201 S. Freeway, Mail Code Q-148
Fort Worth, TX 76134-2099
Attorney Docket No.: 2444 US F



PTO/SB/08A (04-03)

Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	10/534,791
Filing Date	12 May 2005
First Named Inventor	Peter G. KLIMKO et al.
Art Unit	
Examiner Name	
Attorney Docket Number	2444 US F

Sheet 1 of 4

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	A1	US- 5,439,570	08/08/1995	Sessler et al.	
	A2	US- 5,798,349	08/25/1998	Levy et al.	
	A3	US- 5,994,339	11/30/1999	Crapo et al.	
	A4	US- 6,127,356	10/03/2000	Crapo et al.	
	A5	US- 6,177,419	01/23/2001	Campbell et al.	
	A6	US- 6,180,620	01/30/2001	Salvemini	
	A7	US- 6,214,817	04/10/2001	Riley et al.	
	A8	US- 6,541,490	04/01/2003	Campbell et al.	
	A9	US-			
	A10	US-			
	A11	US-			
	A12	US-			
	A13	US-			
	A14	US-			
	A15	US-			
	A16	US-			
	A17	US-			
	A18	US-			
	A19	US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
	A20	WO 98/58636 A1 and A2	12/30/1998	G.D. Searle		
	A21	WO 00/07584 A2 and A3	02/17/2000	Wisconsin Alumni		
	A22	WO 00/19993 A2 and A3	04/13/2000	Brownlee		
	A23	WO 00/72893 A2 and A3	12/07/2000	Monsanto Co.		
	A24					
	A25					

Examiner
SignatureDate
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/534,791
				Filing Date	12 May 2005
				First Named Inventor	Peter G. KLIMKO et al.
				Art Unit	
				Examiner Name	
Sheet	2	of	4	Attorney Docket Number	2444 US F

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	B1	Allikmets R, et al., "Mutation of the Stargardt Disease Gene (ABCR) in Age-Related Macular Degeneration", Science, 277:1805-1807 (1997). Listed as "Dean" in application.	
	B2	Baker et. al., "Synthetic Combined Superoxide Dismutase/Catalase Mimetics Are Protective as a Delayed Treatment in a Rat Stroke Model: A Key Role for Reactive Oxygen Species in Ischemic Brain", J. Pharmacol. Exp. Ther., Vol. 284:215-221, 1998	
	B3	Ben-Shabat et al., "Fluorescent Pigments of the Retinal Pigment Epithelium and Age-Related Macular Degeneration", BIOORGANIC & MEDICINAL CHEMISTRY LETTERS, 11:1533-1540, 2001. Listed as "Nakanishi" in application.	
	B4	Bowler et. al., "A Catalytic Antioxidant (AEOL 10150) Attenuates Expression Of Inflammatory Genes In Stroke", Free Radical Biology & Medicine, Vol. 33(8):1141-1152, 2002	
	B5	Brownlee, M., "Biochemistry and Molecular Cell Biology of Diabetic Complications", Nature, Vol. 414:813-820, 2001	
	B6	Coppey, et al., "Effect of M40403 Treatment of Diabetic Rats on Endoneurial Blood Flow, Motor Nerve Conduction Velocity and Vascular Function of Epineural Arterioles of the Sciatic Nerve," British Journal of Pharmacology, Vol. 134:21-9, 2001 (M40403)	
	B7	Doctrow et. al., "Salen-Manganese Complexes as Catalytic Scavengers of Hydrogen Peroxide and Cytoprotective Agents: Structure-Activity Relationship Studies", J. Med. Chem., 45:4549-4558 (2002)	
	B8	Gürler, et al., "The Role of Oxidative Stress in Diabetic Retinopathy" Eye, Vol. 14:730-735, 2000	
	B9	Guzik, et al., "Mechanisms of Increased Vascular Superoxide Production in Human Diabetes Mellitus" Circulation, Vol. 105:1656-62, 2002	
	B10	Kimura K et al., "Genetic Association of Manganese Superoxide Dismutase With Exudative Age-related Macular Degeneration", AMERICAN JOURNAL OF OPHTHALMOLOGY, 130(6):769-773 (2000). Listed as "Isashiki" in the application.	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	10/534,791
Filing Date	12 May 2005
First Named Inventor	Peter G. KLIMKO et al.
Art Unit	
Examiner Name	
Attorney Docket Number	2444 US F

Sheet

3

of

4

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	C1	Mackensen et. al., "Neuroprotection from Delayed Postischemic Administration of a Metalloprophyrin Catalytic Antioxidant", Journal of Neuroscience, Vol. 21(13):4582-4592, 2001	
	C2	Mata NL et al., "Biosynthesis of a major lipofuscin fluorophore in mice and humans with ABCR-mediated retinal and macular degeneration", Proc. Natl. Acad. Sci. USA, 97(13):7154-7159 (2000). Listed as "Travis" in the application.	
	C3	Melov et. al., "Lifespan Extension and Rescue of Spongiform Encephalopathy in Superoxide Dismutase 2 Nullizygous Mice Treated with Superoxide Dismutase-Catalase Mimetics", J. Neurosci., Vol. 21:8348-8353, 2001	
	C4	Parish et al. (Nakanishi), "Isolation and one-step preparation of A2E and iso-A2E, fluorophores from human retinal pigment epithelium", Proc. Natl. Acad. Sci. USA, 95:14609-14613, 1998	
	C5	Piganelli, et al., "A Metalloporphyrin-Based Superoxide Dismutase Mimic Inhibits Adoptive Transfer of Autoimmune Diabetes by a Diabetogenic T-cell Clone," Diabetes, Vol. 51:347-55, 2002	
	C6	Salvemini D, et. al., "A Nonpeptidyl Mimic of Superoxide Dismutase with Therapeutic Activity in Rats", Science, Vol. 286:304-306, 1999	
	C7	Salvemini, et al., "M40403 Superoxide Dismutase Mimetic", Drugs of The Future, 25(10):1027-1033, 2000	
	C8	Shamsi and Boulton, "Inhibition of RPE Lysosomal and Antioxidant Activity by the Age Pigment Lipofuscin", Invest. Ophthalmol. Vis. Sci., Vol. 42:3041-3046, 2001	
	C9	Shurtz-Swirski et al., "Involvement of Peripheral Polymorphonuclear Leukocytes in Oxidative Stress and Inflammation in Type 2 Diabetic Patients," Diabetes Care, Vol. 24:104-110, 2001	
	C10	Wang et. al., "Tempol, A Superoxide Dismutase Mimic, Ameliorates Light-Induced Retinal Degeneration", Res. Commun. Mol. Pathol. Pharmacol., 89(3):291-305, 1995	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/534,791
				Filing Date	12 May 2005
				First Named Inventor	Peter G. KLIMKO et al.
				Art Unit	
				Examiner Name	
Sheet	4	of	4	Attorney Docket Number	2444 US F

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	D1	Wassell et al., "The Photoreactivity of the Retinal Age Pigment Lipofuscin", J Biol. Chem., 274:23828-23832 (1999) listed as "Boulton" in application	
	D2	Wihlmark et. al., "Lipofuscin Accumulation In Cultured Retinal Pigment Epithelial Cells Causes Enhanced Sensitivity To Blue Light Irradiation", Free Radical Biol. Med, 22:1229-1234, 1997	
	D3	Winkler, et. al., "Oxidative damage and age-related macular degeneration", Mol. Vision, Vol. 5:32, 1999	
	D4	PCT International Search Report for corresponding PCT/US03/38678, mailed October 20, 2004	

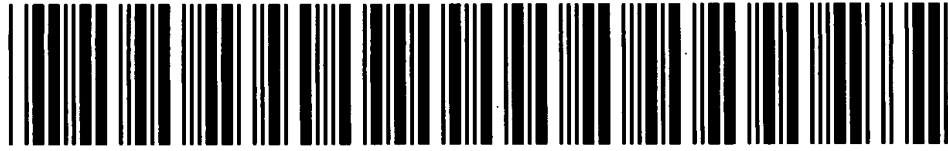
Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

IDS REFERENCES



☐ FOR